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AND G.D. SEARLE LLC

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

IN RE BEXTRA AND CELEBREX MARKETING, SALES PRACTICES AND PRODUCTS LIABILITY LITIGATION *This document relates to* GARY BREWER, et al., Plaintiffs, vs. PFIZER, INC., PHARMACIA CORPORATION, and G.D. SEARLE LLC, (FKA G.D. SEARLE & CO.), Defendants.	MDL Docket No. 1699 CASE NO. 3:07-cv-4031-CRB **PFIZER INC., PHARMACIA CORPORATION, AND G.D. SEARLE LLC'S ANSWER TO COMPLAINT** **JURY DEMAND ENDORSED HEREIN**

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NOW COME Defendants Pfizer Inc. (improperly captioned in Plaintiffs' Complaint as "Pfizer, Inc.") ("Pfizer"), Pharmacia Corporation ("Pharmacia"), and G.D. Searle LLC ("Searle"), (collectively "Defendants") and file this Answer to Plaintiffs' Complaint ("Complaint"), and would respectfully show the Court as follows:

I.

PRELIMINARY STATEMENT

The Complaint does not state in sufficient detail when Plaintiffs were prescribed or used Celebrex® (celecoxib) ("Celebrex®"). Accordingly, this Answer can only be drafted generally. Defendants may seek leave to amend this Answer when discovery reveals the specific time periods in which Plaintiffs were prescribed and used Celebrex®.

II.

ANSWER

Answering the unnumbered paragraph preceding Paragraph 1 of the Complaint, Defendants admit that Plaintiffs brought this civil action seeking monetary damages, but deny that Plaintiffs are entitled to any relief or damages. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the

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Complaint.

Response to Allegations Regarding Parties

1. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Plaintiffs' age, and citizenship, and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

2. Defendants admit that Pfizer is a Delaware corporation with its principal place of business in New York. Defendants admit that, as the result of a merger in April 2003, Pharmacia became a subsidiary of Pfizer. Defendants state that the allegations in this paragraph of the Complaint regarding "predecessors in interest" are vague and ambiguous. Defendants are without knowledge or information sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants admit that, during certain periods of time, Pfizer marketed and co-promoted Celebrex® in the United States, including California, New York, Florida, Missouri, Washington, Alabama, and Michigan, to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

3. Defendants admit that Searle is a Delaware limited liability company with its principal place of business in Illinois. Defendants admit that Pharmacia acquired Searle in 2000 and that, as the result of a merger in April 2003, Searle and Pharmacia became subsidiaries of Pfizer. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

4. Defendants admit that Pharmacia is a Delaware corporation with its principal place of business in New Jersey. Defendants admit that Pharmacia acquired Searle in 2000 and that, as

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the result of a merger in April 2003, Searle and Pharmacia became subsidiaries of Pfizer. Defendants admit that, during certain periods of time, Pharmacia marketed and co-promoted Celebrex® in the United States, including California, New York, Florida, Missouri, Washington, Alabama, and Michigan,, to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

5. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that Pharmacia acquired Searle in 2000 and that, as the result of a merger in April 2003, Searle and Pharmacia became subsidiaries of Pfizer. Defendants deny the remaining allegations in this paragraph of the Complaint.

6. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any

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wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

7. Defendants state that the allegations in this paragraph of the Complaint regarding "predecessors in interest" are vague and ambiguous. Defendants are without knowledge or information sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

Response to Allegations Regarding Jurisdiction and Venue

8. Defendants are without knowledge or information to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Plaintiffs' citizenship and the amount in controversy, and, therefore, deny the same. However, Defendants admit that Plaintiffs claim that the parties are diverse and the amount in controversy exceeds $75,000, exclusive of interests and costs.

9. Defendants are without knowledge or information to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding the judicial district in which the asserted claims allegedly arose and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny committing a tort in the States of California, New York, Florida, Missouri, Washington, Alabama, and Michigan, and deny the remaining allegations in this paragraph of the Complaint.

10. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States, including California, New York, Florida, Missouri, Washington, Alabama, and Michigan, to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that Pfizer, Pharmacia, and Searle are registered to and do business in the States of California,

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New York, Florida, Missouri, Washington, Alabama, and Michigan. Defendants state that the allegations in this paragraph of the Complaint regarding "predecessors in interest" are vague and ambiguous. Defendants are without knowledge or information sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants deny committing a tort in the States of California, New York, Florida, Missouri, Washington, Alabama, and Michigan, and deny the remaining allegations in this paragraph of the Complaint.

Response to Allegations Regarding Interdistrict Assignment

11. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendants admit that this case should be transferred to In re: Bextra and Celebrex Marketing, Sales Prac. and Prods. Liab. Litig., MDL-1699, assigned to the Honorable Charles R. Breyer by the Judicial Panel on Multidistrict Litigation on September 6, 2005.

Response to Factual Allegations

12. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Plaintiff's age, citizenship, medical condition, and whether Plaintiff used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

13. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Plaintiff's age, citizenship, medical condition, and whether Plaintiff used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of

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Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

14. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Plaintiff's age, citizenship, medical condition, and whether Plaintiff used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

15. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Plaintiff's age, citizenship, medical condition, and whether Plaintiff used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

16. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Plaintiff's age, citizenship, medical condition, and whether Plaintiff used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of

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Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

17. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Plaintiff's age, citizenship, medical condition, and whether Plaintiff used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

18. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Plaintiff's age, citizenship, medical condition, and whether Plaintiff used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

19. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Plaintiff's age, citizenship, medical condition, and whether Plaintiff used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of

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Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

20. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Plaintiff's age, citizenship, medical condition, and whether Plaintiff used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

21. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Plaintiff's age, citizenship, medical condition, and whether Plaintiff used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

22. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Plaintiff's age, citizenship, medical condition, and whether Plaintiff used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of

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Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

23. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny that Celebrex® caused Plaintiffs injury or damage and deny the remaining allegations in this paragraph of the Complaint.

24. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or damage and deny the remaining allegations in this paragraph of the Complaint.

25. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used Celebrex® and, therefore, deny the same. Defendants state that, in the ordinary case, Celebrex® was expected to reach users and consumers without substantial change from the time of sale. Defendants deny the remaining allegations in this paragraph of the Complaint.

26. Defendants are without knowledge or information sufficient to form a belief as to the

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truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

27. Defendants state that Plaintiffs fail to provide the proper context for the allegations in this paragraph of the Complaint regarding "Decedents." Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding such allegations. and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint, including all subparts.

28. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

29. Defendants state that the allegations in this paragraph of the Complaint regarding aspirin, naproxen, and ibuprofen are not directed toward Defendants, and, therefore, no response is required. Defendants admit that Celebrex® is in a class of drugs that are, at times, referred to as being non-steroidal anti-inflammatory drugs ("NSAIDs"). Defendants deny the remaining allegations in this paragraph of the Complaint.

30. Defendants state that the allegations in this paragraph of the Complaint are not directed towards Defendants and, therefore, no response is required. To the extent that a response is deemed required, Defendants state that Plaintiffs fail to provide the proper context for the

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allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

31. Defendants state that the allegations in this paragraph of the Complaint are not directed towards Defendants and, therefore, no response is required. To the extent that a response is deemed required, Defendants state that Plaintiffs fail to provide the proper context for the allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

32. Defendants state that the allegations in this paragraph of the Complaint are not directed towards Defendants and, therefore, no response is required. To the extent that a response is deemed required, Defendants state that Plaintiffs fail to provide the proper context for the allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

33. Defendants state that the allegations in this paragraph of the Complaint regarding "other pharmaceutical companies" are not directed towards Defendants and, therefore, no response is required. To the extent a response is deemed required, Defendants state that, as stated in the FDA-approved labeling for Celebrex®, "[t]he mechanism of action of Celebrex is believed to be due to inhibition of prostaglandin synthesis, primarily via inhibition of cyclooxygenase-2 (COX-2), and at therapeutic concentrations in humans, Celebrex does not inhibit the cyclooxygenase-1 (COX-1) isoenzyme." Plaintiffs fail to provide the proper context for the remaining allegations in this paragraph and Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of the allegations and, therefore, deny the remaining allegations in this paragraph of the Complaint.

34. Defendants state that the allegations in this paragraph of the Complaint regarding "predecessors in interest" are vague and ambiguous. Defendants are without knowledge or information sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants state that, as stated in the FDA-approved labeling for Celebrex®, "[t]he mechanism of action of Celebrex is believed to be due to inhibition of prostaglandin synthesis,

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primarily via inhibition of cyclooxygenase-2 (COX-2), and at therapeutic concentrations in humans, Celebrex does not inhibit the cyclooxygenase-1 (COX-1) isoenzyme." Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

35. Defendants admit that Searle submitted a New Drug Application ("NDA") for Celebrex® on June 29, 1998. Defendants admit that, on December 31, 1998, the FDA granted approval of Celebrex® for the following indications: (1) for relief of the signs and symptoms of osteoarthritis; and (2) for relief of the signs and symptoms of rheumatoid arthritis in adults. Defendants admit that, on December 23, 1999, the FDA granted approval of Celebrex® to reduce the number of adenomatous colorectal polyps in familial adenomatous polyposis ("FAP") as an adjunct to usual care (e.g. endoscopic surveillance surgery). Defendants deny the remaining allegations in this paragraph of the Complaint.

36. Defendants admit that Celebrex® was launched in February 1999. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the

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remaining allegations in this paragraph of the Complaint.

37. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny the remaining allegations in this paragraph of the Complaint.

38. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny the remaining allegations in this paragraph of the Complaint.

39. Defendants state that the referenced FDA Update speaks for itself and respectfully refer the Court to the FDA Update for its actual language and text. Any attempt to characterize the FDA Update is denied. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny the remaining allegations in this paragraph of the Complaint.

40. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny the remaining allegations in this paragraph of the Complaint.

41. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information,

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which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

42. Defendants admit that a supplemental NDA for Celebrex® was submitted to the FDA on June 12, 2000. Defendants assert that the submission speaks for itself and any attempt to characterize it is denied. Defendants admit that a Medical Officer Review dated September 20, 2000, was completed by the FDA. Defendants state that the referenced study speaks for itself and respectfully refer the Court to the study for its actual language and text. Any attempt to characterize the study is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

43. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

44. Defendants state that the referenced study speaks for itself and respectfully refer the Court to the study for its actual language and text. Any attempt to characterize the study is denied. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

45. Defendants state that the transcripts of the FDA Arthritis Drugs Advisory Committee hearings speak for themselves and respectfully refer the Court to the transcripts for their actual language and text. Any attempt to characterize the transcripts is denied. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

46. Defendants state that the transcripts of the FDA Arthritis Drugs Advisory Committee hearings speak for themselves and respectfully refer the Court to the transcripts for their actual language and text. Any attempt to characterize the transcripts is denied. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

47. Defendants state that the referenced articles speak for themselves and respectfully refer the Court to the articles for their actual language and text. Any attempt to characterize the

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articles is denied. Defendants state that the referenced study speaks for itself and respectfully refer the Court to the study for its actual language and text. Any attempt to characterize the study is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

48. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

49. Defendants state that the referenced articles speak for themselves and respectfully refer the Court to the articles for their actual language and text. Any attempt to characterize the articles is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

50. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants state that the referenced study speaks for itself and respectfully refer the Court to the study for its actual language and text. Any attempt to characterize the study is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

51. Defendants state that the referenced Medical Officer Review speaks for itself and respectfully refer the Court to the Medical Officer Review for its actual language and text. Any attempt to characterize the Medical Officer Review is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

52. Plaintiffs fail to provide the proper context for the allegations concerning "Public Citizen" in this paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

53. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants deny any wrongful conduct and deny the remaining allegations in this

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paragraph of the Complaint.

54. Defendants state that the referenced study speaks for itself and respectfully refer the Court to the study for its actual language and text. Any attempt to characterize the study is denied. Plaintiffs fail to provide the proper context for the allegations concerning "Public Citizen" in this paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

55. Defendants admit that there was a clinical trial called APC. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

56. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Plaintiffs fail to provide the proper context for the allegations concerning "Data Safety Monitoring Board" in this paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

57. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

58. Defendants state that the referenced Alert for Healthcare Professionals speaks for itself and respectfully refer the Court to the Alert for Healthcare Professionals for its actual language and text. Any attempt to characterize the Alert for Healthcare Professionals is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

59. Defendants state that the referenced Medical Officer Review speaks for itself and respectfully refer the Court to the Medical Officer Review for its actual language and text. Any attempt to characterize the Medical Officer Review is denied. Defendants deny the remaining

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allegations in this paragraph of the Complaint.

60. Defendants admit that there was a clinical trial called PreSAP. Plaintiffs fail to provide the proper context for the allegations concerning "other Celebrex trials" contained in this paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same. As for the allegations in this paragraph of the Complaint regarding the PreSAP study, Defendants state that the referenced study speaks for itself and respectfully refer the Court to the study for its actual language and text. Any attempt to characterize the study is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

61. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

62. Plaintiffs fail to provide the proper context for the allegations in this paragraph of the Complaint regarding Merck and Vioxx® in this paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same. Defendants state that the referenced studies speak for themselves and respectfully refer the Court to the studies for their actual language and text. Any attempt to characterize the studies is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

63. Defendants state that the referenced Medical Officer Review speaks for itself and respectfully refer the Court to the Medical Officer Review for its actual language and text. Any attempt to characterize the Medical Officer Review is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

64. Defendants state that allegations regarding Vioxx® in this paragraph of the Complaint are not directed toward Defendants, and therefore no response is required. To the extent that a response is deemed required, Plaintiffs fail to provide the proper context for the allegations in this paragraph of the Complaint regarding Vioxx® in this paragraph of the Complaint.

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Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same. Defendants state that the referenced study speaks for itself and respectfully refer the Court to the study for its actual language and text. Any attempt to characterize the study is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

65. Defendants state that allegations regarding Merck and Vioxx® in this paragraph of the Complaint are not directed toward Defendants, and therefore no response is required. To the extent that a response is deemed required, Plaintiffs fail to provide the proper context for the allegations in this paragraph of the Complaint regarding Merck and Vioxx® in this paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same. Defendants state that the referenced study speaks for itself and respectfully refer the Court to the study for its actual language and text. Any attempt to characterize the study is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

66. Defendants state that allegations regarding Merck and Vioxx® in this paragraph of the Complaint are not directed toward Defendants, and therefore no response is required. To the extent that a response is deemed required, Plaintiffs fail to provide the proper context for the allegations in this paragraph of the Complaint regarding Merck and Vioxx® in this paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same. Defendants state that the referenced study speaks for itself and respectfully refer the Court to the study for its actual language and text. Any attempt to characterize the study is denied. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

67. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny the allegations in this

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paragraph of the Complaint.

68. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

69. Defendants state that allegations in this paragraph of the Complaint are not directed toward Defendants, and therefore no response is required. To the extent that a response is deemed required, Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

70. Defendants deny the allegations in this paragraph of the Complaint.

71. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the remaining allegations contained in this paragraph of the Complaint.

72. Defendants deny any wrongful conduct and deny the allegations contained in this paragraph of the Complaint.

73. Defendants deny any wrongful conduct and deny the allegations contained in this paragraph of the Complaint.

74. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations contained in this paragraph of the Complaint.

75. Defendants are without knowledge or information sufficient to form a belief as to the

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truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® is unreasonably dangerous, and deny the remaining allegations in this paragraph of the Complaint.

76. Defendants admit that the FDA Division of Drug Marketing, Advertising, and Communications ("DDMAC") sent letters to Searle dated October 6, 1999, April 6, 2000, and November 14, 2000. Defendants state that the referenced letters speak for themselves and respectfully refer the Court to the letters for their actual language and text. Any attempt to characterize the letters is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

77. Defendants admit that the DDMAC sent a letter to Pharmacia dated February 1, 2001. Defendants state that the referenced letter speaks for itself and respectfully refer the Court to the letter for its actual language and text. Any attempt to characterize the letter is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

78. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

79. Defendants admit that the DDMAC sent a letter to Pfizer dated January 10, 2005. Defendants state that the referenced letter speaks for itself and respectfully refer the Court to the letter for its actual language and text. Any attempt to characterize the letter is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

80. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of

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Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

81. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that Celebrex® is a prescription medication which is approved by the FDA for the following indications: (1) for relief of the signs and symptoms of osteoarthritis; (2) for relief of the signs and symptoms of rheumatoid arthritis in adults; (3) for the management of acute pain in adults; (4) for the treatment of primary dysmenorrhea; (5) to reduce the number of adenomatous colorectal polyps in familial adenomatous polyposis (FAP) as an adjunct to usual care (e.g., endoscopic surveillance surgery); (6) for relief of signs and symptoms of ankylosing spondylitis; and (7) for

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relief of the signs and symptoms of juvenile rheumatoid arthritis in patients two years of age and older. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

82. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which at all times was adequate and comported with applicable standards of care and law. Defendants state that Plaintiffs' allegations regarding "predecessors in interest" are vague and ambiguous. Defendants are without knowledge or information to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the allegations in this paragraph of the Complaint.

83. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

84. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which at all times was adequate and comported with applicable standards of care and law.

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Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

85. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

86. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

87. Defendants deny the allegations in this paragraph of the Complaint.

88. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

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89. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

90. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used Celebrex® and, therefore, deny the same. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

91. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the remaining allegations in this paragraph of the Complaint.

92. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® are and were adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

93. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

94. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used

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Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® are and were adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

Response to First Cause of Action: Negligence

95. Defendants incorporate by reference their responses to each paragraph of Plaintiffs' Complaint as if fully set forth herein.

96. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendants admit that they had duties as are imposed by law but deny having breached such duties. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

97. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendants admit that they had duties as are imposed by law but deny having breached such duties. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

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98. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint, including all subparts.

99. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

100. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

101. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-

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approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

102. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Plaintiffs' medical conditions and whether Plaintiffs used Celebrex®, and, therefore, deny the same. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

103. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

104. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

Response to Second Cause of Action: Strict Liability

105. Defendants incorporate by reference their responses to each paragraph of Plaintiffs' Complaint as if fully set forth herein.

106. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used Celebrex®, and, therefore, deny the same. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that, in the ordinary case, Celebrex® was expected to reach users and consumers without substantial change from the time of sale. Defendants deny the remaining

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allegations in this paragraph of the Complaint.

107. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny the remaining allegations in this paragraph of the Complaint.

108. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny that Celebrex® is defective or unreasonably dangerous and deny the remaining allegations in this paragraph of the Complaint.

109. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny that Celebrex® is defective or unreasonably dangerous and deny the remaining allegations in this paragraph of the Complaint, including all subparts.

110. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® is defective, deny that Celebrex® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

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111. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the remaining allegations in this paragraph of the Complaint.

112. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® is defective, deny that Celebrex® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

113. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

114. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with

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applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

115. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

116. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

117. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

118. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

119. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

Response to Third Cause of Action: Breach of Express Warranty

120. Defendants incorporate by reference their responses to each paragraph of Plaintiffs' Complaint as if fully set forth herein.

121. Defendants are without knowledge or information sufficient to form a belief as to the

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truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants admit that they provided FDA-approved prescribing information regarding Celebrex®. Defendants deny the remaining allegations in this paragraph of the Complaint.

122. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants admit that they provided FDA-approved prescribing information regarding Celebrex®. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint, including all subparts.

123. Defendants admit that they provided FDA-approved prescribing information regarding Celebrex®. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

124. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

125. Defendants state that Celebrex® was and is safe and effective when used in accordance

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with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

126. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used Celebrex®, and, therefore, deny the same. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants admit that they provided FDA-approved prescribing information regarding Celebrex®. Defendants deny the remaining allegations in this paragraph of the Complaint.

127. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

128. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

129. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

Response to Fourth Cause of Action: Breach of Implied Warranty

130. Defendants incorporate by reference their responses to each paragraph of Plaintiffs' Complaint as if fully set forth herein.

131. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law

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authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

132. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants admit that they provided FDA-approved prescribing information regarding Celebrex®. Defendants deny the remaining allegations in this paragraph of the Complaint.

133. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny the remaining allegations in this paragraph of the Complaint.

134. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that they breached any warranty, and deny the remaining allegations in this paragraph of the Complaint.

135. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® is a prescription medication which is approved by the FDA for the following indications: (1) for relief of the signs and symptoms of osteoarthritis; (2) for relief of the signs and symptoms of rheumatoid arthritis in adults; (3) for the management of acute pain in adults; (4) for the treatment of

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primary dysmenorrhea; (5) to reduce the number of adenomatous colorectal polyps in familial adenomatous polyposis (FAP) as an adjunct to usual care (e.g., endoscopic surveillance surgery); (6) for relief of signs and symptoms of ankylosing spondylitis; and (7) for relief of the signs and symptoms of juvenile rheumatoid arthritis in patients two years of age and older. Defendants deny the remaining allegations in this paragraph of the Complaint.

136. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants admit that they provided FDA-approved prescribing information regarding Celebrex®. Defendants deny the remaining allegations in this paragraph of the Complaint.

137. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used Celebrex® and, therefore, deny the same. Defendants state that, in the ordinary case, Celebrex® was expected to reach users and consumers without substantial change from the time of sale. Defendants deny the remaining allegations in this paragraph of the Complaint.

138. Defendants are without knowledge or information sufficient to form a belief as to the truth of theallegations in this paragraph of the Complaint regarding whether Plaintiffs used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that they breached any warranty, and deny the remaining allegations in this paragraph of the Complaint.

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139. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

140. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

141. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

Response to Fifth Cause of Action: Fraudulent Misrepresentation and Concealment

142. Defendants incorporate by reference their responses to each paragraph of Plaintiffs' Complaint as if fully set forth herein.

143. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendants admit that they had duties as are imposed by law but deny having breached such duties. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

144. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint, including all subparts.

145. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information,

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which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

146. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® is defective or unreasonably dangerous, and deny the remaining allegations in this paragraph of the Complaint.

147. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

148. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

149. Defendants are without knowledge or information sufficient to form a belief as to the

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truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

150. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

151. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

152. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants

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state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

153. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

154. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

155. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

156. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

Response to Sixth Cause of Action: Unjust Enrichment

157. Defendants incorporate by reference their responses to each paragraph of Plaintiffs' Complaint as if fully set forth herein.

158. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law

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authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

159. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used Celebrex® and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

160. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used Celebrex® and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

161. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

162. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

163. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or

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damage, and deny the remaining allegations in this paragraph of the Complaint.

Response to Seventh Cause of Action:

State Consumer Fraud and Deceptive Trade Practices Act

164. Defendants incorporate by reference their responses to each paragraph of Plaintiffs' Complaint as if fully set forth herein.

165. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendants admit that they had duties as are imposed by law but deny having breached such duties. Defendants deny the remaining allegations in this paragraph of the Complaint.

166. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiffs used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

167. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiffs used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

168. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiffs used Celebrex® and, therefore, deny the

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same. Defendants deny the remaining allegations in this paragraph of the Complaint.

169. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiffs used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

170. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

171. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

172. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

173. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

174. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

175. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

Response to Prayer For Relief

Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or damage, and deny the remaining allegations in paragraph of the Complaint headed "Prayer for Relief," including all subparts.

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III.

GENERAL DENIAL

Defendants deny all allegations and/or legal conclusions set forth in Plaintiffs' Complaint that have not been previously admitted, denied, or explained.

IV.

AFFIRMATIVE DEFENSES

Defendants reserve the right to rely upon any of the following or additional defenses to claims asserted by Plaintiffs to the extent that such defenses are supported by information developed through discovery or evidence at trial. Defendants affirmatively show that:

First Defense

1. The Complaint fails to state a claim upon which relief can be granted.

Second Defense

2. Celebrex® is a prescription medical product. The federal government has preempted the field of law applicable to the labeling and warning of prescription medical products. Defendants' labeling and warning of Celebrex® was at all times in compliance with applicable federal law. Plaintiffs' causes of action against Defendants, therefore, fail to state a claim upon which relief can be granted; such claims, if allowed, would conflict with applicable federal law and violate the Supremacy Clause of the United States Constitution.

Third Defense

3. At all relevant times, Defendants provided proper warnings, information and instructions for the drug in accordance with generally recognized and prevailing standards in existence at the time.

Fourth Defense

4. At all relevant times, Defendants' warnings and instructions with respect to the use of Celebrex® conformed to the generally recognized, reasonably available, and reliable state of knowledge at the time the drug was manufactured, marketed and distributed.

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Fifth Defense

5. Plaintiffs' action is time-barred as it is filed outside of the time permitted by the applicable Statute of Limitations, and same is pled in full bar of any liability as to Defendants.

Sixth Defense

6. Plaintiffs' action is barred by the statute of repose.

Seventh Defense

7. Plaintiffs' claims against Defendants are barred to the extent Plaintiffs were contributorily negligent, actively negligent or otherwise failed to mitigate their damages, and any recovery by Plaintiffs should be diminished accordingly.

Eighth Defense

8. The proximate cause of the loss complained of by Plaintiffs is not due to any acts or omissions on the part of Defendants. Rather, said loss is due to the acts or omissions on the part of third parties unrelated to Defendants and for whose acts or omissions Defendants are not liable in any way.

Ninth Defense

9. The acts and/or omissions of unrelated third parties as alleged constituted independent, intervening causes for which Defendants cannot be liable.

Tenth Defense

10. Any injuries or expenses incurred by Plaintiffs were not caused by Celebrex®, but were proximately caused, in whole or in part, by an idiosyncratic reaction, operation of nature, or act of God.

Eleventh Defense

11. Defendants affirmatively deny that they violated any duty owed to Plaintiffs.

Twelfth Defense

12. A manufacturer has no duty to warn patients or the general public of any risk, contraindication, or adverse effect associated with the use of a prescription medical product. Rather, the law requires that all such warnings and appropriate information be given to the

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prescribing physician and the medical profession, which act as a "learned intermediary" in determining the use of the product. Celebrex® is a prescription medical product, available only on the order of a licensed physician. Celebrex® provided an adequate warning to Plaintiffs' treating and prescribing physicians.

Thirteenth Defense

13. The product at issue was not in a defective condition or unreasonably dangerous at the time it left the control of the manufacturer or seller.

Fourteenth Defense

14. Celebrex® was at all times material to the Complaint reasonably safe and reasonably fit for its intended use and the warnings and instructions accompanying Celebrex® at the time of the occurrence of the injuries alleged by Plaintiffs were legally adequate for its approved usages.

Fifteenth Defense

15. Plaintiffs' causes of action are barred in whole or in part by the lack of a defect as the Celebrex® allegedly ingested by Plaintiffs was prepared in accordance with the applicable standard of care.

Sixteenth Defense

16. Plaintiffs' alleged injuries/damages, if any, were the result of misuse or abnormal use of the product Celebrex® after the product left the control of Defendants and any liability of Defendants is therefore barred.

Seventeenth Defense

17. Plaintiffs' alleged damages were not caused by any failure to warn on the part of Defendants.

Eighteenth Defense

18. Plaintiffs' alleged injuries/damages, if any, were the result of preexisting or subsequent conditions unrelated to Celebrex®.

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Nineteenth Defense

19. Plaintiffs knew or should have known of any risk associated with Celebrex®; therefore, the doctrine of assumption of the risk bars or diminishes any recovery.

Twentieth Defense

20. Plaintiffs are barred from recovering against Defendants because Plaintiffs' claims are preempted in accordance with the Supremacy Clause of the United States Constitution and by the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 301 et. seq.

Twenty-first Defense

21. Plaintiffs' claims are barred in whole or in part under the applicable state law because the subject pharmaceutical product at issue was subject to and received pre-market approval by the Food and Drug Administration under 52 Stat. 1040, 21 U.S.C. § 301.

Twenty-second Defense

22. The manufacture, distribution and sale of the pharmaceutical product referred to in Plaintiffs' Complaint were at all times in compliance with all federal regulations and statutes, and Plaintiffs' causes of action are preempted.

Twenty-third Defense

23. Plaintiffs' claims are barred in whole or in part by the deference given to the primary jurisdiction of the Food and Drug Administration over the subject pharmaceutical product at issue under applicable federal laws, regulations, and rules.

Twenty-fourth Defense

24. Plaintiffs' claims are barred in whole or in part because there is no private right of action concerning matters regulated by the Food and Drug Administration under applicable federal laws, regulations, and rules.

Twenty-fifth Defense

25. Plaintiffs' claims are barred in whole or in part because Defendants provided adequate "direction or warnings" as to the use of the subject pharmaceutical product within the meaning of Comment j to Section 402A of the Restatement (Second) of Torts.

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Twenty-sixth Defense

26. Plaintiffs' claims are barred or limited to a product liability failure to warn claim because Celebrex® is a prescription pharmaceutical drug and falls within the ambit of Restatement (Second) of Torts § 402A, Comment k.

Twenty-seventh Defense

27. Plaintiffs' claims are barred in whole or in part because the subject pharmaceutical product at issue "provides net benefits for a class of patients" within the meaning of Comment f to § 6 of the Restatement (Third) of Torts: Products Liability.

Twenty-eighth Defense

28. Plaintiffs' claims are barred under § 4, et seq., of the Restatement (Third) of Torts: Products Liability.

Twenty-ninth Defense

29. To the extent that Plaintiffs are seeking punitive damages, Plaintiffs have failed to plead facts sufficient under the law to justify an award of punitive damages.

Thirtieth Defense

30. Defendants affirmatively aver that the imposition of punitive damages in this case would violate Defendants' rights to procedural due process under the Fourteenth Amendment of the United States Constitution and the Constitutions of the States of California, New York, Florida, Missouri, Washington, Alabama, and Michigan,and would additionally violate Defendants' rights to substantive due process under the Fourteenth Amendment of the United States Constitution.

Thirty-first Defense

31. Plaintiffs' claims for punitive damages are barred, in whole or in part, by the Fifth and Fourteenth Amendments to the United States Constitution.

Thirty-second Defense

32. The imposition of punitive damages in this case would violate the First Amendment to the United States Constitution.

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Thirty-third Defense

33. Plaintiffs' punitive damage claims are preempted by federal law.

Thirty-fourth Defense

34. In the event that reliance was placed upon Defendants' nonconformance to an express representation, this action is barred as there was no reliance upon representations, if any, of Defendants.

Thirty-fifth Defense

35. Plaintiffs failed to provide Defendants with timely notice of any alleged nonconformance to any express representation.

Thirty-sixth Defense

36. To the extent that Plaintiffs' claims are based on a theory providing for liability without proof of causation, the claims violate Defendants' rights under the United States Constitution.

Thirty-seventh Defense

37. Plaintiffs' claims are barred, in whole or in part, because the advertisements, if any, and labeling with respect to the subject pharmaceutical products were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the United States Constitution.

Thirty-eighth Defense

38. To the extent that Plaintiffs seek punitive damages for the conduct which allegedly caused injuries asserted in the Complaint, punitive damages are barred or reduced by applicable law or statute or, in the alternative, are unconstitutional insofar as they violate the due process protections afforded by the United States Constitution, the excessive fines clause of the Eighth Amendment of the United States Constitution, the Commerce Clause of the United States Constitution, and the Full Faith and Credit Clause of the United States Constitution, and applicable provisions of the Constitutions of the States of California, New York, Florida, Missouri, Washington, Alabama, and Michigan. Any law, statute, or other authority purporting to permit the recovery of punitive damages in this case is unconstitutional, facially and as

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applied, to the extent that, without limitation, it: (1) lacks constitutionally sufficient standards to guide and restrain the jury's discretion in determining whether to award punitive damages and/or the amount, if any; (2) is void for vagueness in that it failed to provide adequate advance notice as to what conduct will result in punitive damages; (3) permits recovery of punitive damages based on out-of-state conduct, conduct that complied with applicable law, or conduct that was not directed, or did not proximately cause harm, to Plaintiffs; (4) permits recovery of punitive damages in an amount that is not both reasonable and proportionate to the amount of harm, if any, to Plaintiffs and to the amount of compensatory damages, if any; (5) permits jury consideration of net worth or other financial information relating to Defendants; (6) lacks constitutionally sufficient standards to be applied by the trial court in post-verdict review of any punitive damages awards; (7) lacks constitutionally sufficient standards for appellate review of punitive damages awards; and (8) otherwise fails to satisfy Supreme Court precedent, including, without limitation, *Pacific Mutual Life Ins. Co. v. Haslip*, 499 U.S. 1, 111 (1991), *TXO Production Corp. v. Alliance Resources, Inc.*, 509 U.S. 443 (1993); *BMW of North America, Inc. v. Gore*, 519 U.S. 559 (1996); and *State Farm Mut. Auto Ins. Co. v. Campbell*, 538 U.S. 408 (2003).

Thirty-ninth Defense

39. The methods, standards, and techniques utilized with respect to the manufacture, design, and marketing of Celebrex®, if any, used in this case, included adequate warnings and instructions with respect to the product's use in the package insert and other literature, and conformed to the generally recognized, reasonably available, and reliable state of the knowledge at the time the product was marketed.

Fortieth Defense

40. The claims asserted in the Complaint are barred because Celebrex® was designed, tested, manufactured and labeled in accordance with the state-of-the-art industry standards existing at the time of the sale.

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Forty-first Defense

41. If Plaintiffs have sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were caused by the actions of persons not having real or apparent authority to take said actions on behalf of Defendants and over whom Defendants had no control and for whom Defendants may not be held accountable.

Forty-second Defense

42. The claims asserted in the Complaint are barred, in whole or in part, because Celebrex® was not unreasonably dangerous or defective, was suitable for the purpose for which it was intended, and was distributed with adequate and sufficient warnings.

Forty-third Defense

43. Plaintiffs' claims are barred, in whole or in part, by the equitable doctrines of laches, waiver, and/or estoppel.

Forty-fourth Defense

44. Plaintiffs' claims are barred because Plaintiffs' injuries, if any, were the result of the pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases or illnesses, subsequent medical conditions or natural courses of conditions of Plaintiffs, and were independent of or far removed from Defendants' conduct.

Forty-fifth Defense

45. The claims asserted in the Complaint are barred, in whole or in part, because Celebrex® did not proximately cause injuries or damages to Plaintiffs.

Forty-sixth Defense

46. The claims asserted in the Complaint are barred, in whole or in part, because Plaintiffs did not incur any ascertainable loss as a result of Defendants' conduct.

Forty-seventh Defense

47. The claims asserted in the Complaint are barred, in whole or in part, because the manufacturing, labeling, packaging, and any advertising of the product complied with the applicable codes, standards and regulations established, adopted, promulgated or approved by

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any applicable regulatory body, including but not limited to the United States, any state, and any agency thereof.

Forty-eighth Defense

48. The claims must be dismissed because Plaintiffs would have taken Celebrex® even if the product labeling contained the information that Plaintiffs contend should have been provided.

Forty-ninth Defense

49. The claims asserted in the Complaint are barred because the utility of Celebrex® outweighed its risks.

Fiftieth Defense

50. Plaintiffs' damages, if any, are barred or limited by the payments received from collateral sources.

Fifty-first Defense

51. Defendants' liability, if any, can only be determined after the percentages of responsibility of all persons who caused or contributed toward Plaintiffs' alleged damages, if any, are determined. Defendants seek an adjudication of the percentage of fault of the claimants and each and every other person whose fault could have contributed to the alleged injuries and damages, if any, of Plaintiffs.

Fifty-second Defense

52. Plaintiffs' claims are barred, in whole or in part, by the doctrine of abstention in that the common law gives deference to discretionary actions by the United States Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act.

Fifty-third Defense

53. The claims asserted in the Complaint are barred, in whole or in part, because Celebrex® is comprehensively regulated by the FDA pursuant to the Federal Food, Drug & Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq*., and regulations promulgated there under, and Plaintiffs' claims conflict with the FDCA, with the regulations promulgated by FDA to implement the

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FDCA, with the purposes and objectives of the FDCA and FDA's implementing regulations, and with the specific determinations by FDA specifying the language that should be used in the labeling accompanying Celebrex®. Accordingly, Plaintiffs' claims are preempted by the Supremacy Clause of the United States Constitution, Article VI, clause 2, and the laws of the United States.

Fifty-fourth Defense

54. Plaintiffs' misrepresentation allegations are not stated with the degree of particularity required by Federal Rule of Civil Procedure 9(b) and should be dismissed.

Fifty-fifth Defense

55. Defendants state on information and belief that the Complaint and each purported cause of action contained therein is barred by the statutes of limitations contained in California Code of Civil Procedure §§ 335.1 and 338 and former § 340(3), and such other statutes of limitation as may apply.

Fifty-sixth Defense

56. Defendants state on information and belief that any injuries, losses, or damages suffered by Plaintiffs were proximately caused, in whole or in part, by the negligence or other actionable conduct of persons or entities other than Defendants. Therefore, Plaintiffs' recovery against Defendants, if any, should be reduced pursuant to California Civil Code § 1431.2.

Fifty-seventh Defense

57. To the extent that Plaintiffs seek punitive damages for an alleged act or omission of Defendants, no act or omission was oppressive, fraudulent, or malicious under California Civil Code § 3294, and, therefore, any award of punitive damages is barred. Any claim for punitive damages is also barred under California Civil Code § 3294(b).

Fifty-eighth Defense

58. The products in question were approved as safe and effective by the FDA and the labeling for said products were in compliance with FDA's approval at the time the products left the control of one or more Defendants and hence, Plaintiffs' claims are barred by MCL

600.2946(5).

Fifty-ninth Defense

59. Plaintiffs' claim for non-economic damages is capped pursuant to MCL 600.2946a.

Sixtieth Defense

60. To the extent Plaintiffs prove that the products in question caused or contributed to any injury Plaintiffs may have suffered, which is denied by these Defendants, these Defendants should not be liable to warn as Plaintiffs cannot prove that the scientific, technical or medical information that was reasonably available at the time was known or should have been known by the Defendants. MCL 600.2948.

Sixty-first Defense

61. Defendants assert all of the protections and defenses afforded them, and Plaintiffs' claims of liability or damages are limited pursuant to the Michigan Products Liability Act including specifically, but not limited to MCL 600.2946 through MCL 600.6306, including MCL 600.2946, MCL 600.2946(a), MCL 600.2947, MCL 600.2948, MCL 600.2956, MCL 600.2957 and MCL 600.2959.

Sixty-second Defense

62. The products alleged to have caused damages may not have been used in the manner and for the purposes intended. Such improper use and/or abuse of the products for an unforeseeable purpose and in an unforeseeable manner may have proximately caused or contributed to the alleged injuries, if any, and therefore there is no recovery available against Defendants pursuant to MCL 600.2947.

Sixty-third Defense

63. Plaintiffs' claim for non-economic damages is barred for the reason that Plaintiffs' percentage of comparative fault is greater than the aggregate fault of the Defendants and non-parties hereto, pursuant to MCL 600.2959 and MCL 600.6306; but that to the extent allowable, must be reduced in total or part pursuant to 600.2946(a).

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Sixty-fourth Defense

64. The claims set forth in Plaintiffs' Complaint are barred in that the products in question were provided to a sophisticated user. In this case, the "user" would include any prescribing physician.

Sixty-fifth Defense

65. Plaintiffs failed to make every reasonable effort to mitigate, prevent and/or reduce their alleged damages, injuries, and monetary losses.

Sixty-sixth Defense

66. Plaintiffs' claims, part of Plaintiffs' claims, or evidence relating to Plaintiffs' claims may be barred in whole or in part due to possible spoliation of evidence by Plaintiffs, or those within Plaintiffs' control or with full knowledge of Plaintiffs.

Sixty-seventh Defense

67. Any claims for punitive damages are barred in that they are not allowable under Michigan law. To the extent that they are allowed contrary to Michigan law, such claims further violate Defendants' constitutional rights under the following clauses of the United States Constitution, as well as any similar provisions under the Michigan Constitution: Commerce Clause, Contracts Clause, Supremacy Clause, Due Process, Takings Clause, Excessive Fines and Equal Protection.

Sixty-eighth Defense

68. Plaintiffs' fraud-based claims, if any, are not stated with particularity as required by Rule 1.120 of the Florida Rules of Civil Procedure.

Sixty-ninth Defense

69. Plaintiffs' claims are barred because Celebrex® was designed, manufactured, and marketed in accordance with the state of the art at the time of manufacture per § 768.1257, Florida Statutes.

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Seventieth Defense

70. Celebrex® is not defective or unreasonably dangerous, and Defendants are not liable because, at the time of sale or distribution of the Celebrex® alleged to have been used by Plaintiffs, Defendants had complied with applicable regulations of the federal Food & Drug Administration and are entitled to application of § 768.1256, Florida Statutes.

Seventy-first Defense

71. Plaintiffs' injuries and damages, if any, were proximately caused by the negligence or fault of Plaintiffs, or persons or parties whose identities are unknown at this time, and such comparative negligence or fault is sufficient to proportionately reduce or bar Plaintiffs' recovery. Thus, Defendants are entitled to have their liability to the Plaintiffs, if any, reduced as a result of the negligence or fault of said persons or entities, pursuant to the provisions of § 768.81, Florida Statutes. To the extent any recovery is permitted in this case, pursuant to §§ 768.31 and 768.81, Florida Statutes, judgment must be entered on the basis of Defendants' percentage of fault, taking into account the percentage of fault attributable to all other persons, whether or not a party hereto, and not on the basis of joint and several liability. The persons or entities referred to in this paragraph that are presently unknown to Defendants will be identified in a timely manner consistent with *Nash v. Wells Fargo*, 678 So. 2d 1262 (Fla. 1996).

Seventy-second Defense

72. Plaintiffs fail to state a claim for violation of The Florida Deceptive and Unfair Trade Practices Act ("FDUTPA").

Seventy-third Defense

73. FDUTPA does not apply to claims for personal injuries, and, accordingly, Plaintiffs' FDUTPA claim is improper and should be dismissed.

Seventy-fourth Defense

74. The acts or practices of which Plaintiffs complain were and are required or specifically permitted by federal or state law. Therefore, Plaintiffs' FDUTPA claim is barred, fails to state a claim, and should be dismissed with prejudice.

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Seventy-fifth Defense

75. Plaintiffs lack standing because Defendants did not engage in deceptive conduct with regard to Plaintiffs or otherwise.

Seventy-sixth Defense

76. In the event Plaintiffs recover a verdict or judgment against Defendants, then said verdict or judgment must be reduced pursuant to CPLR 4545(c), and/or other applicable State or Commonwealth statutes, by those amounts which have, or will, with reasonable certainty, replace or indemnify Plaintiffs, in whole or in part, for any past or future claimed medical expenses or other such economic loss, paid from any collateral source such as insurance, social security, workers' compensation or employee benefit programs.

Seventy-seventh Defense

77. In accordance with CPLR 1601 et seq., and/or other applicable State or Commonwealth statutes, the liability of Defendants, if any, to Plaintiffs for non-economic loss is limited to its equitable share, determined in accordance with the relative culpability of all persons or entities contributing to the total liability for non-economic loss, including named parties and others over whom Plaintiffs could have obtained personal jurisdiction with due diligence.

Seventy-eighth Defense

78. In accordance with General Obligations Law 15-108, if Plaintiffs execute a release or a covenant not to sue for a tortfeasor in this action, Plaintiffs' damage claim against Defendants is reduced to the extent of any amount stipulated by the release or covenant, or in the amount of consideration paid for it, or in the amount of the released tortfeasor's equitable share of the damages under CPLR 1401 et seq., whichever is greatest.

Seventy-ninth Defense

79. The conduct of Defendants and all activities with respect to the subject products were fair and truthful based upon the knowledge existing at the relevant time alleged in the Complaint. Therefore, Plaintiffs' claims under New York Business Corporation Law § 349 are barred.

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Eightieth Defense

80. Plaintiffs' claims are barred by the limitations and defenses set out in the Missouri Product Liability Act, Mo. Rev. Stat. § 537. 760 *et seq.*, including but not limited to, the "state of the art" defenses as defined in Mo. Rev. Stat. § 537.764. Defendants incorporate by reference all defenses and/or limitations set forth or referenced in the Missouri Product Liability Act.

Eighty-first Defense

81. The proximate cause of the loss complained of by Plaintiffs is not due to any acts or omissions on the part of Defendants. Rather, said loss is due to the acts or omissions on the part of third parties unrelated to Defendants and for whose acts or omissions Defendants is not liable in any way. Mo. Rev. Stat. § 537.765.

Eighty-second Defense

82. The imposition of punitive damages in this case would violate Defendants' rights to procedural due process under both the Fourteenth Amendment of the United States Constitution and Article I, § 17 of the Constitution of the State of Missouri, and would additionally violate Defendants' right to substantive due process under the Fourteenth Amendment of the United States Constitution.

Eighty-third Defense

83. Plaintiff's claims for punitive damages are barred, in whole or in part, by the Fifth and Fourteenth Amendments to the United States Constitution and are subject to all provisions of Missouri law.

Eighty-fourth Defense

84. Defendants deny that they are liable for any damages in this case. Defendants contend, however, that any damage award to Plaintiffs that utilizes the Missouri joint and several liability scheme would be unconstitutional, as this scheme is violative of Defendants' due process and equal protection guarantees under the United States and Missouri Constitutions. The Missouri joint and several liability scheme, under Mo. Rev. Stat. § 537.067, violates

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Defendants' due process guarantees because no legitimate state interest supports § 537.067, and, furthermore, no rational relationship exists between a legitimate state interest and the promotion of the Missouri joint and several liability scheme. Additionally, the Missouri system of assessing joint and several liability violates Defendants' equal protection guarantees because it operates to create arbitrary classifications of individuals, and to treat similarly situated individuals dissimilarly under the law. The joint and several liability scheme is also unconstitutionally void for vagueness under the United States and Missouri Constitutions. Thus, the scheme is unconstitutional and should not be applied in this action.

Eighty-fifth Defense

85. The imposition of punitive damages pursuant to current Alabama law violates the Due Process and Equal Protection provisions of the Fourteenth Amendment to the United States Constitution; to wit, Defendants have not been given fair notice of the standard of conduct which could subject them to a claim for punitive damages, and have not been given fair notice of the amount of punitive damages that may accompany a finding of liability. Alabama's current laws regarding punitive damages do not serve a rational or legitimate state interest.

Eighty-sixth Defense

86. Defendants plead the applicability of the Washington Products Liability Act, RCW 7.72 et seq., and specially aver that Plaintiffs' common law claims are preempted by the statute and must be dismissed.

Eighty-seventh Defense

87. Defendants reserve the right to supplement their assertion of defenses as they continue with their factual investigation of Plaintiffs' claims.

V.

PRAYER

WHEREFORE, Defendants pray for judgment as follows:

1. That Plaintiffs take nothing from Defendants by reason of the Complaint;

2. That the Complaint be dismissed;

3. That Defendants be awarded their costs for this lawsuit;

4. That the trier of fact determine what percentage of the combined fault or other liability of all persons whose fault or other liability proximately caused Plaintiffs' alleged injuries, losses or damages is attributable to each person;

5. That any judgment for damages against Defendants in favor of Plaintiffs be no greater than an amount which equals their proportionate share, if any, of the total fault or other liability which proximately caused Plaintiffs' injuries and damages; and

6. That Defendants have such other and further relief as the Court deems appropriate.

October 12, 2007

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JURY DEMAND

Defendants Pfizer Inc., Pharmacia Corporation, and G.D. Searle LLC hereby demand a trial by jury of all the facts and issues in this case pursuant to 38(b) of the Federal Rules of Civil Procedure.

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